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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,200	01/03/2003	Peter D. Kwong	54203-H-PCT-US/JPW/SHS	3857

7590

09/20/2005

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New York, NY 10036

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,200

Applicant(s)

KWONG ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

5.00

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1, 21, 27-28, 33-34, 36-38, 42, 44-49, 53, 55-59, 61, 80-81, 83-86, 90-91, and 94 are pending in the application.

[3] Applicants' preliminary amendment to the claims and the specification, filed on 5/13/2003, is acknowledged.

[4] Receipt of an information disclosure statement, filed on 11/5/2004, is acknowledged.

[5] In order to perfect a claim for domestic priority, the relationship of each of the priority applications as stated in the priority claim should be identified and the current status of priority applications should be updated in the first paragraph of the specification.

Lack of Unity

[6] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 1 and 21, drawn to the special technical feature of a crystal and a method for producing a crystal.

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Group II, claims 27-28 and 37-38, drawn to the special technical feature of a method for identifying or designing a compound capable of binding to a portion of HIV-gp120, including a compound that binds to the CD4 binding site on HIV-gp120.

Group III, claims 33-34, 42, 44-46, 61, 80-81, and 83, drawn to the special technical feature of a compound or a composition or pharmaceutical composition thereof that binds to a portion of HIV-gp120, including a compound that binds to the CD4 binding site on HIV-gp120.

Group IV, claim 36, drawn to the special technical feature of a method of inhibiting the interaction of HIV-gp120 with CD4.

Group V, claims 47 and 84-85, drawn to the special technical feature of a method of inhibiting HIV infection in a subject by administering a composition comprising a compound that binds to the CD4 binding site on HIV-gp120.

Group VI, claims 27-28 and 48-49, drawn to the special technical feature of a method for identifying or designing a compound capable of binding to a portion of HIV-gp120, including a compound that binds to the chemokine receptor binding site on HIV-gp120.

Group VII, claims 33-34, 53, and 55-57, drawn to the special technical feature of a compound or a composition or pharmaceutical composition thereof that binds to a portion of HIV-gp120, including a compound that binds to the chemokine receptor binding site on HIV-gp120.

Group VIII, claim 58, drawn to the special technical feature of a method of inhibiting HIV infection in a subject by administering a composition comprising a compound that binds to the chemokine receptor binding site on HIV-gp120.

Group IX, claim 59, drawn to the special technical feature of a method of inhibiting the interaction of HIV-gp120 with chemokine receptor.

Group X, claims 86 and 90, drawn to the special technical feature of a variant of gp120 and a vaccine comprising said variant.

Group XI, claim 91, drawn to the special technical feature of a method for inducing an antibody against HIV using a variant of gp120.

Group XII, claim 94, drawn to the special technical feature of an antibody against a variant of gp120.

[7] The technical feature linking groups is an HIV gp120 polypeptide and crystal thereof. The inventions listed as Groups I-XII do not relate to a single general inventive

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concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-XII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. In this case, the crystal of Group I was known in the art at the time of the invention. Claim 1 is drawn to a crystal...comprising a polypeptide having an amino acid sequence of a portion of an HIV gp120 polypeptide. As a "portion" can be a single amino acid, the claim encompasses any protein crystal that is "suitable for X-ray diffraction." Such crystals were well-known in the art at the time of the invention. See, e.g., Kwong et al. (*Nature* 393:648-659; cited in the IDS filed 11/5/2004). Thus, the technical feature is shown to lack novelty or inventive step, and does not make the special technical feature a contribution over the prior art.
- According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The crystal of Group I, the compounds of Groups III and VII, the HIV gp120 variant of Group X, and the antibody of Group XII share no special technical feature as the crystal of Group I is not limited to the polypeptide of Group X, the compounds of Groups III and VII do not necessarily bind to the polypeptide of Group X, and the antibody of Group XII encompasses antibodies that bind to polypeptides besides the polypeptide of Group X.
- According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The crystal of Group I and the methods of Groups II, IV, V, VI, VIII, IX, and XI share no special technical feature as each of the inventions of Groups I-II, IV-VI, VIII-IX, and XI has a different special technical feature.

[8] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[9] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim


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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs and alternate Fri, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656

Continuation of Disposition of Claims: Claims pending in the application are 1,21,27,28,33,34,36-38,42,44-49,53,55-59,61,80,81,83-86,90,91 and 94.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,21,27,28,33,34,36-38,42,44-49,53,55-59,61,80,81,83-86,90,91 and 94.